Grand Valley State University Office of Research Compliance and Integrity (ORCI) – Human Research Administrative Standard Operating Procedure	
Title: *HRRC protocol review*	
Section: 900	RIO Approval Date: 10/13/2014
Initial Approval Date:	Previous Revision Dates: New Policy
Related Documents: *121: Review standards for research not covered by FWA* *910: Continuing review and approval of selected non-exempt protocols* *911: Exemption determinations and research ethics standards*	

POLICY

Role and authority of the HRRC chair in protocol review:

1 The chair may be consulted by any board or staff member for assistance in reviewing any aspect of any protocol.

2 The chair may review and make an approval or other determination for any protocol under exempt or expedited review procedures at any time without a second reviewer.

3 In severely time sensitive conditions, the chair may review and act upon revisions or amendments submitted for any previously tabled or approved exempt or expedited protocol even if not one of the assigned reviewer(s) of the initial protocol submission.

4 In exceptional circumstances involving immediate threat of harm to one or more study participants, the chair or the RIO unilaterally may suspend the research project, or call an emergency meeting of a quorum of the board for addressing the potential for harm to study participants. Lifting of a protocol suspension requires a majority vote of the board with quorum at a convened meeting.

5 For exempt or expedited reviews only, if the reviewers disagree on the proper action, the chair will serve as a third reviewer. If the chair disagrees with the recommended action he will refer the matter to a vice-chair or other discipline expert HRRC member for additional review until a majority agreement is reached.

6 The chair will fulfill the same roles and responsibilities as the board members as noted below.

Role and responsibilities of board members in protocol review

Board members are to become and maintain current familiarity with pertinent Federal regulations, State law and University policies related to use of Human Subjects in Research. They are to make approval recommendations on all research proposals to which they are assigned for review by the deadline specified unless prior notification to the ORCI office is submitted. They are to review assigned materials and prepare for, attend and actively participate in all regular and special meetings of the HRRC unless excused by the chair or unable to participate because of emergency situations, teaching conflicts or disclosed conflicts of interest.

PROCEDURES

The HRRC reviews research proposals in accordance with the applicable regulatory criteria for approval as well as state law, university and ORCI policies. The HRRC chair votes as a regular member of the board at will. HRRC Board members are assigned protocol submissions by the HRRC Chair or staff designee. There are two designations of board members: regular members and designated reviewers (DR).

Regular members are new members still in training and with less experience reviewing protocols. They are initially assigned protocol reviews as a second reviewer on exempt studies or third reviewer on expedited studies until the HRRC Chair determines that they have sufficient expertise and protocol review experience to warrant the status of designated reviewer (DR). Regular members' votes count equally toward protocol approval.

For exempt studies, DRs are authorized to unilaterally review and make certain determinations regarding review level and category.

For expedited reviews, DRs are authorized to serve as one of a pair of reviewers for expedited protocols, and to make approval decisions regarding initial submission, minor or major amendments or revisions to previously approved protocols, including continuing reviews. DRs may not suspend, terminate or disapprove a protocol submission but may refer it to the full board for further consideration

1. Preliminary determination of exempt status is made by authorized ORCI staff when reviewing research protocol submissions to the HRRC for approval. . In addition, selected ORCI staff may re-grade a protocol as not research, as not involving living human subjects or upgrade the review category to expedited review or full board review based upon their administrative review. The protocol file is then assigned to an HRRC member for review and status recommendation to the Chair for concurrence and inclusion or objection and explanation in the final review determination letter. ORCI staff do not conduct expedited reviews or approve any major changes to approved protocols. They may acknowledge minor changes to approved protocols per SOP 020 *Major vs. Minor*.

2. For each protocol of any level of review each assigned reviewer will:
   2.1 Use the "Checklist: Criteria for Approval and Additional Considerations" and all referenced checklists (listed below) to have the convened HRRC determine which regulatory criteria are met, which are not met, and which would be met if the investigator modified the protocol as requested by the reviewer.
   2.1.1 State the reviewer's analysis regarding protocol specific findings justifying determinations when required by the relevant checklists.

3. Make a motion for one of the following actions:

   3.1.1 **"Approve**": The initial, continuing, or modification submission meets all the criteria for approval. For initial and continuing review, include in the motion the period of approval.
   3. 1.2 Period of approval will be for two (2) years unless prohibited by categories noted below in 3.1.3.
   3.1.3 Approval not to exceed maximum of 1 year if:
      (i) greater than minimal risk
      (ii) federally funded
      (iii) sponsor restricted
      (iv) student led
      (v) FDA regulated
      (vi) prisoners as study participants.

   3 .2 **"Approve with Conditions":** The initial, continuing, or modification submission will meet the criteria for approval with minor or prescriptive changes or

requirements that can be verified by administrative staff without considering the criteria for approval.

3.2.1. For initial and continuing review, include in the motion the period of approval and the level of risk minimal risk.

3.2.2. Summarize the IRB's required modifications and reasons.

3.3 **"Defer" (table):** The initial, continuing, or modification submission does not meet the criteria for approval and also does not meet the criteria for "Disapprove".

3.3.1. Summarize the IRB's reasons (required clarifications and modifications) and recommendations, if any.

3.3.2 If required clarifications are *major,* 3.2 above (Approve with Conditions) does not apply and the response to tabling letter must be accepted or declined by

3.3.2.1 the HRRC or Vice-Chair acting as chair

3.3.2.2 the full board

3.4. "**Disapprove**": The initial, continuing, or modification submission does not meet the criteria for approval and the full IRB at a convened meeting considers the research to have extensive deficiencies. This motion is Not Available FOR EXEMPT OR EXPEDITED REVIEWS.

3.4.1. Motion should be to refer to full board for review

3.4.2 Summarize the IRB's reasons and recommendations, if any.

3.5. "**Suspend**": Based on new information the previously approved research no longer meets the criteria for approval, but some research activities meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.

3.5.1. Include in the motion: Which research activities must stop or be modified

3.5.2. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment

3.5.3. If stopping research will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed

3.5.4. Summarize the IRB's reasons and recommendations.

3.5.5 Refer to the full board and to RIO. Follow HRRC policy #1050: *Suspension or Termination of Research Activities* including all reporting requirements.

3.6. "**Terminate**": Based on new information the previously approved research no longer meets the criteria for approval and the IRB has no recommendations to make the research approvable. Must be referred to full board and if termination is action is approved, reports to affected federal agencies may also be required, e.g. OHRP, FDA, NSF, etc,

3.6.1. Summarize the IRB's reasons.

3.6.2 Refer to the full board and RIO. Follow HRRC policy #1050: *Suspension or Termination of Research Activities* including all reporting requirements.

3.7. "**Lift Suspension**": Based on a modification submission (Change in protocol) or new information the previously suspended research meets the criteria for approval. Requires full board approval at a convened meeting

3.8 **"Decline to Review"**. If reviewer(s) determines submission is insufficiently prepared, and Chair concurs, the motion is to Table without action; the status is withdrawn; the determination letter states Decline to Review.

3.81 Summarize the IRB's reasons.

3.9 "**Waiver or alteration"** of consent process or documentation of consent requested by PI or appropriate to suggest to the PI as determined by an HRRC reviewer. Must be documented as a separate vote from the protocol approval itself.

3.91 **Expedited review**. Approval requires majority reviewer agreement including a final review and determination by the chair or a vice-chair. Requires three votes if using DR, two votes if only chair and vice-chair.

3.92 **Full board review**. Approval of a waiver or alteration of the consent process or documentation requires majority vote of members present at [1]convened meeting and documented as a separate vote from the protocol approval determination.

Options for IRB members present but not voting on a motion

4 **"Abstain"** Based on lack of opportunity to formally review and form measured judgments concerning the protocol submission the member does not participate in the voting. The abstention is not global to the protocol; it may affect only initial application or any subsequent submission of the same protocol.

4.1 **"Recuse"** Due to a previously declared conflicted interest or other real or apparent competing influence the member excuses him or herself from the discussion and voting on the initial protocol submission or any subsequent submissions. Recusal is global to the protocol file.

REFERENCES

3.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.
3.2 45 CFR §46.109, §46.116, §46.117.

[1] Convened meeting indicates quorum has been met; recusals count as absences and therefore may not contribute to quorum. Abstentions are not absences and do count toward quorum, but as a no vote. Quorum is achieved by the presence of one over half of the full voting members and must include at least one non-scientist. An alternate member may count toward quorum when any full voting member is absent. Votes involving prisoners as study subjects must include the prisoner representative.